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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,254	REED ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-52 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-5, and 11-13 drawn to **ONE** isolated polypeptide and chimeric thereof selected from the group consisting of SEQ ID Nos: 2, 4, 6, 8, 10, 12, 16, 18, 20, 22, 26, 53, 56, or 58, classified in class 530, subclass 350.

   Upon election of Group 1, applicant must select ONE polypeptide from those listed above as each polypeptide represents an independent and/or distinct invention, not a species. Further, Claims 11-13 will only be examined to the extent that they read on the elected invention.

2. Claims 6-8, 10, drawn to ONE isolated antibody having specific reactivity to ONE polypeptide listed in Claim 5 or ONE polypeptide of SEQ ID NO:18 or 22, classified in class 530, subclass 387.1.

   Upon election of Group 2, applicant must select ONE antibody from those listed above as each antibody represents an independent and/or distinct invention, not a species. Further, Claim 7 will only be examined to the extent that it reads on the elected invention.

3. Claim 9, drawn to ONE cell line producing ONE monoclonal antibody, classified in class 435, subclass 326.

Upon election of Group 3, applicant must select ONE cell line which produces ONE antibody from those set forth in Group II as each cell represents an independent and/or distinct invention, not a species.

4. Claims 14-21,23 drawn to **ONE** isolated nucleic acid molecule that encodes ONE of the polypeptides selected from the group consisting of SEQ ID Nos: 2, 4, 6, 8, 10, 12, 16, 18, 20, 22, 26, 53, 56, or 58, classified in class 536, subclass 23.5; class 435, subclasses 69.1, 320.1, 325

Upon election of Group 4, applicant must select ONE nucleic acid (NA) molecule from those listed above as each NA represents an independent and/or distinct invention, not a species. Further, Claims 15-16, 18-21, and 23 will only be examined to the extent that they read on the elected invention.

5. Claim 22 drawn to **ONE** kit for detecting the presence of ONE cDNA sequence comprising ONE oligonucleotide from Claim 20, classified in class 435, subclass 810.

Upon election of Group 5, applicant must select ONE oligonucleotide from those listed in Claim 20 for the purpose of detecting ONE cDNA molecule as each kit represents an independent and/or distinct invention, not a species.

6. Claim 24, drawn to a method of detecting **ONE** nucleic acid molecule that encodes ONE polypeptide comprising contacting a sample containing said nucleic

acid with ONE oligonucleotide from those listed in Claim 20, classified in class 435, subclass 6.

Upon election of Group 6, applicant must select ONE oligonucleotide from those listed in Claim 20 for the purpose of detecting ONE nucleic acid molecule as the detection of each NA represents an independent and/or distinct invention, not a species.

7. Claim 25, drawn to a method of detecting **ONE** antibody:DD, DED, or NB-ARC domain complex comprising contacting a sample with ONE antibody from those listed in Claim 6, classified class 435, subclass 7.1.

Upon election of Group 7, applicant must select ONE antibody from those listed in Claim 6 for the purpose of detecting ONE antibody:polypeptide complex as the detection of each complex represents an independent and/or distinct invention, not a species.

8. Claims 26-29 drawn to a method of identifying a binding agent comprising contacting **one** DD, DED, or NB-ARC domain from **one** DAP3, IRAK4, CTDD, DED4, or NIDD with said binding agent and detecting the association of said domain and said agent wherein said detecting is by **yeast two hybrid assay**, classified class 435, subclass 4, 7.31.

Upon election of Group 8, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each binding agent represents an independent and/or distinct invention, not a species.

9. Claims 26-29 drawn to a method of identifying a binding agent comprising contacting **one** DD, DED, or NB-ARC domain from **one** DAP3, IRAK4, CTDD, DED4, or NIDD with said binding agent and detecting the association of said domain and said agent wherein said detecting is by **immunoprecipitation**, classified class 435, subclass 7.92.

Upon election of Group 9, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each binding agent represents an independent and/or distinct invention, not a species.

10. Claims 26-29 drawn to a method of identifying a binding agent comprising contacting **one** DD, DED, or NB-ARC domain from **one** DAP3, IRAK4, CTDD, DED4, or NIDD with said binding agent and detecting the association of said domain and said agent wherein said detecting is by **SPA**, classified class 436, subclass 57.

Upon election of Group 10, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each binding agent represents an independent and/or distinct invention, not a species.

11. Claims 26-29 drawn to a method of identifying a binding agent comprising contacting **one** DD, DED, or NB-ARC domain from **one** DAP3, IRAK4, CTDD, DED4, or NIDD with said binding agent and detecting the association of said domain and said agent wherein said detecting is by **UV or chemical crosslinking,** classified class 435, subclass 448.

Upon election of Group 11, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each binding agent represents an independent and/or distinct invention, not a species.

12. Claims 26-29 drawn to a method of identifying a binding agent comprising contacting **one** DD, DED, or NB-ARC domain from **one** DAP3, IRAK4, CTDD, DED4, or NIDD with said binding agent and detecting the association of said domain and said agent wherein said detecting is by **NMR and or MS**, classified class 436, subclass 173.

Upon election of Group 12, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each binding agent represents an independent and/or distinct invention, not a species.

13. Claims 26-29 drawn to a method of identifying a binding agent comprising contacting **one** DD, DED, or NB-ARC domain from **one** DAP3, IRAK4, CTDD, DED4, or NIDD with said binding agent and detecting the association of said

domain and said agent wherein said detecting is by **FPA**, classified class 436, subclass 172.

Upon election of Group 13, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each binding agent represents an independent and/or distinct invention, not a species.

14. Claims 30-31, 34-35 drawn to a method of identifying an agent that modulates the association of **one** DD, DED, or NB-ARC domain wherein said DD, DED, or NB-ARC domain is from **one** DAP3, IRAK4, CTDD, DED4, or NIDD wherein said detecting is by **yeast two hybrid assay**, classified class 435, subclass 4, 7.31.

Upon election of Group 14, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each modulator represents an independent and/or distinct invention, not a species.

15. Claims 30-31, 34-35 drawn to a method of identifying an agent that modulates the association of **one** DD, DED, or NB-ARC domain wherein said DD, DED, or NB-ARC domain is from **one** DAP3, IRAK4, CTDD, DED4, or NIDD wherein said detecting is by **immunoprecipitation**, classified class 435, subclass 7.92.

Upon election of Group 15, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each modulator represents an independent and/or distinct invention, not a species.

16. Claims 30-31, 34-35 drawn to a method of identifying an agent that modulates the association of **one** DD, DED, or NB-ARC domain wherein said DD, DED, or NB-ARC domain is from **one** DAP3, IRAK4, CTDD, DED4, or NIDD wherein said detecting is by **SPA**, classified class 436, subclass 57.

Upon election of Group 16, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each modulator represents an independent and/or distinct invention, not a species.

17. Claims 30-31, 34-35 drawn to a method of identifying an agent that modulates the association of **one** DD, DED, or NB-ARC domain wherein said DD, DED, or NB-ARC domain is from **one** DAP3, IRAK4, CTDD, DED4, or NIDD wherein said detecting is by **UV or chemical crosslinking**, classified class 435, subclass 448.

Upon election of Group 17, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each modulator represents an independent and/or distinct invention, not a species.

18. Claims 30-31, 34-35 drawn to a method of identifying an agent that modulates the association of **one** DD, DED, or NB-ARC domain wherein said DD, DED, or NB-ARC domain is from **one** DAP3, IRAK4, CTDD, DED4, or NIDD wherein said detecting is by **NMR and or MS**, classified class 436, subclass 173.

Upon election of Group 18, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each modulator represents an independent and/or distinct invention, not a species.

19. Claims 30-31, 34-35 drawn to a method of identifying an agent that modulates the association of **one** DD, DED, or NB-ARC domain wherein said DD, DED, or NB-ARC domain is from **one** DAP3, IRAK4, CTDD, DED4, or NIDD wherein said detecting is by **FPA**, classified class 436, subclass 172.

Upon election of Group 19, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each modulator represents an independent and/or distinct invention, not a species.

20. Claims 30, 32, 34-35 drawn to a method of identifying an agent that modulates the association of **one** DD, DED, or NB-ARC domain wherein said DD, DED, or NB-ARC domain is from **one** DAP3, IRAK4, CTDD, DED4, or NIDD wherein said detecting is by measuring the activity of NF-KB, classified class 435, subclass 4.

Upon election of Group 20, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each modulator represents an independent and/or distinct invention, not a species.

21. Claims 30, 33-35 drawn to a method of identifying an agent that modulates the association of **one** DD, DED, or NB-ARC domain wherein said DD, DED, or NB-ARC domain is from **one** DAP3, IRAK4, CTDD, DED4, or NIDD wherein said detecting is by measuring the activity of caspase-8, classified class 435, subclass 23.

Upon election of Group 21, applicant must select ONE domain and only one DAP3, IRAK4, CTDD, DED4, or NIDD as the identification of each modulator represents an independent and/or distinct invention, not a species.

22. Claims 36-37 drawn to a method of modulating a cell process comprising contacting a cell with ONE agent identified by the method of Claim 30 wherein said cell process is ONE process selected from the group consisting of apoptosis, cell proliferation, cell adhesion, cell stress responses, responses to microbial infections, or B-cell immunoglobulin class switching, classified class 435, subclass 4.

Upon election of Group 22, applicant must select ONE agent and only ONE cell process from those listed above as each agent and each process represents an independent and/or distinct invention, not a species. Further, Claim 37 will only be examined to the extent that it reads on the elected subject matter.

23. Claims 38-42 drawn to a method of modulating ONE activity mediated by a DD, DED or NB-ARC domain, comprising contacting ONE domain of a DD, DED or NB-ARC domain cell with ONE agent identified by the method of Claim 30 wherein said activity is ONE activity selected from the group consisting of:

binding of DD to a protein that binds a DD domain protein

binding of DD to a protein that binds to a DED domain protein

binding of DD to a protein that binds to NB-ARC domain protein

binding of DED to a protein that binds a DD domain protein

binding of DED to a protein that binds to a DED domain protein

binding of DED to a protein that binds to NB-ARC domain protein

binding of NB-ARC to a protein that binds a DD domain protein

binding of NB-ARC to a protein that binds to a DED domain protein

binding of NB-ARC to a protein that binds to NB-ARC domain

NF-KB activity

Caspase activity

Apoptosis activity

Cell proliferation activity

Cell adhesion activity

Cell stress response activity

Responses to microbial infection activity

B-cell immunoglobulin class switching activity, classified class 435, subclass 4.

Upon election of Group 23, applicant must select ONE agent and only ONE activity from those listed above as each agent and each activity represents an independent and/or distinct invention, not a species. Further, Claims 40-42 will only be examined to the extent that it reads on the elected subject matter.

24. Claims 43-44 drawn to a method of modulating the level of ONE cell process comprising introducing ONE nucleic acid molecule encoding either a DD, DED, or NB-ARC domain wherein said domain is from ONE domain of either DAP3, IRAK4, CTDD, DED4, or NIDD, wherein said cell process is ONE process selected from the group consisting of apoptosis, cell proliferation, cell adhesion, cell stress responses, responses to microbial infections, or B-cell immunoglobulin class switching, classified class 435, subclasses 440, 6.

Upon election of Group 24, applicant must select nucleic acid and only ONE cell process from those listed above as each nucleic acid and each process represents an independent and/or distinct invention, not a species. Further, Claim 44 will only be examined to the extent that it reads on the elected subject matter.

25. Claims 45-46 drawn to a method modulating ONE cell process by reducing or inhibiting the expression of ONE molecule wherein said molecule is DD, DED, or NB-ARC comprising introducing an antisense molecule into a cell wherein said cell process is either apoptosis, cell proliferation, cell adhesion, cell stress

responses, responses to microbial infections, or B-cell immunoglobulin class switching, classified class 435, subclass 375.

Upon election of Group 25, applicant must select one antisense molecule specific for DD, DED, or NB-ARC and only ONE cell process from those listed above as antisense and process represents an independent and/or distinct invention, not a species. Further, Claim 46 will only be examined to the extent that it reads on the elected subject matter.

26. Claim 47, drawn to a method modulating a cell process comprising contacting a cell with ONE compound selected from the group consisting of a DD domain, a DED domain, a NB-ARC domain, a fragment of said domains, an agent identified in Claim 30, an anti-DD antibody, anti-DED antibody, anti-NB-ARC antibody, classified class 435, subclass 4.

Upon election of Group 26, applicant must select only one compound as each compound represents an independent and/or distinct invention, not a species. Further, applicant should identify only one domain from DAP3, IRAK4, DED4 or NIDD.

27. Claims 48-49, in part, drawn to a method of diagnosing a pathology comprising contacting a test sample with ONE agent wherein said agent is an antibody selected from the group consisting of an anti-DD, or an anti-DED, or an anti-NB-ARC domain antibody, classified in Class 435, subclass 7.1.

Upon election of Group 27, applicant must select only one agent as each agent represents an independent and/or distinct invention, not a species. Further, applicant should identify only one domain from DAP3, IRAK4, CTDD, DED4 or NIDD.

28. Claims 48-49, in part, drawn to a method of diagnosing a pathology comprising contacting a test sample with ONE agent wherein said agent is selected from the group consisting of FADD, caspase-8, caspase-10, DR4, DR5, Traf6, hToll, MyD88, Fas, Raidd, IRAK, IRAK-2, IRAK-m, p75NTR, Tradd, DAP kinase, RIP< NMP84, ankyrins, Flip, PEA15, Flash, BAP31, BAR, DEDT/DEDD, CTDD, or DAP3. classified in Class 435, subclass 7.1.

Upon election of Group 28, applicant must select only one agent as each agent represents an independent and/or distinct invention, not a species. Further, applicant should identify only one domain from DAP3, IRAK4, CTDD, DED4 or NIDD.

29. Claim 50, drawn to a method of diagnosing a pathology characterized by an increase or decreased level of ONE domain (either DD or DED or NP-ARC) comprising contacting a test sample with ONE oligonucleotide according to Claim 20, classified in Class 435, subclass 6.

Upon election of Group 29, applicant must select only one oligonucleotide as the use of each oligonucleotide represents an independent and/or distinct

invention, not a species. Further, applicant should identify only one domain from DAP3, IRAK4, CTDD, DED4 or NIDD.

30. Claim 51, drawn to a method of detecting a Chlamydia infection comprising contacting a test sample with ONE antibody specifically reactive with ONE polypeptide, classified in Class 435, subclasses 7.1, 7.36.
Upon election of Group 30, applicant must select only one antibody as the use of each antibody represents an independent and/or distinct invention, not a species.

31. Claim 52, drawn to a method of detecting a Chlamydia infection comprising contacting a nucleic acid containing test sample from a subject with ONE nucleic acid molecule encoding ONE sequence, classified in Class 435, subclasses 6, 7.36.
Upon election of Group 31, applicant must select only one nucleic acid as the use of each nucleic acid represents an independent and/or distinct invention, not a species.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups 1-5 represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The inventions of Groups 6-31 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The invention of Group 1 and the methods of Groups 8-23,26 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the peptide product as claimed can be used in a materially different process such as affinity chromatography.

The invention of Group 2 and the methods of Groups 7-9, 15, 26-27, 30 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography.

The invention of Group 4 and the methods of Groups 6, 24-25, 29, 31 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid product as claimed can be used in a materially different process such as affinity chromatography.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
September 12, 2003